REMARKS

In the communication mailed June 9, 2003, the Office required an election of one of the following restricted groups of claims:

Group I (claims 13-17, 19-20, 23-30): drawn to a diagnosis reagent comprising a recombinant antigen and a single synthetic antigen of HCV antigen, classified in class 424, subclass 228; and

Group II (claims 13-15, 18, 21-22, 24-30): drawn to a diagnostic reagent comprising a recombinant HCV antigen and three synthetic HCV antigens, classified in class 424, subclass 202.1.

The applicants respectfully traverse this restriction requirement. The Office has impermissibly restricted subject matter within a single claim, independent claim 13, and has separated subject matter away from the subject matter of the independent claim (*e.g.*, claims 19 and 23) that will be covered by the same search required for the independent claim.

The Office has Impermissibly Restricted Within a Single Claim

Claim 13 is directed to a diagnostic reagent for hepatitis C virus (HCV) infection **comprising** a solid phase sensitized with a genetic recombinant HCV antigen and **a** synthesized HCV antigen. Controlling legal precedent has established that patent claim parlance recognizes the article "a" can carry the meaning of "one or more," especially in a claim using the transitional phrase "comprising." *See e.g., Elkay Manufacturing Co. v. Ebco. Manufacturing Co.*, 52 USPQ.2d 1109, 1112 (Fed. Cir. 1999), citing *Abtox, Inc. v. Exitron Corp.*, 43 USPQ.2d 1545, 1548 (Fed. Cir. 1997), which cites *North Am. Vaccine, Inc. v. American Cyanamid Co.*, 28 USPQ.2d 1333, 1336 (Fed. Cir. 1993). As claim 13 includes the transitional term "comprising" and the specification makes it clear that "one or more" synthesized antigens can be utilized in the claimed methods (*see e.g.*, specification at page 2, lines 4-12 and page 7, lines 24-37), the article "a" in the claim refers to one or more synthesized antigens. Although it is clear that the Office has interpreted the article "a" in claim 13 as referring to "one or more" synthesized antigens, the applicants amend claim 13 herein such that it explicitly refers to "one or more" synthesized HCV antigens.

Because claim 13 is directed to a reagent comprising a genetic recombinant HCV antigen and one or more synthesized HCV antigens, the Office has impermissibly restricted claim 13

between one synthesized HCV antigen and three synthesized HCV antigens. It has long been held that the Office may not impose a restriction requirement on a single claim. *See In re Watkinson*, 14 USPQ.2d 1407 (Fed. Cir. 1990) citing *In re Weber*, 198 USPQ 328, 332 (CCPA 1978) and *In re Haas*, 198 USPQ 334, 336 (CCPA 1978). The courts have definitively ruled that the statute authorizing restriction practice (*i.e.* 35 U.S.C. § 121) provides no authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. In these cases, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Office to fashion such a rejection. As noted in *In re Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim, no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber at 334.

Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim because the claim cannot issue as drafted. In this regard the courts noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not effect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim will never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of fragments would not be described in the specification.

See In re Weber , *supra,* emphasis added.

Instead of improperly imposing a restriction requirement on a given claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim (*see* 37 C.F.R. § 1.146). This practice strikes an appropriate balance between administrative concerns of the Office and the clear constitutional and statutory rights of the inventor to claim an invention as it is contemplated. *See* MPEP at § 803.02; *In re Wolfrum*, 179 USPQ 620 (CCPA 1973); and *In re Kuehl*, 177 USPQ 250 (CCPA 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution nor does it force an applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. Here, it should be clear that the added cost of filing and prosecuting multiple patent applications does not strike an appropriate balance between the administrative concerns of the Office and the applicants' statutory rights as inventors.

There is No Undue Search Burden for Examining Dependent Claims

In Group II, the Office did not include the subject matter of claims 16, 17, 19-20 and 23. It is respectfully submitted that the search required for claim 13 should cover the subject matter of claims 19 and 23, which are directed to one or more synthesized antigens being conjugated to a carrier protein. As the search for the diagnostic reagent of claim 13 should also yield results pertinent to the carrier proteins referenced in claims 19 and 23, it is respectfully requested that the Office include the subject matter of claims 19 and 23 in the examination of the elected claims pursuant to MPEP § 803(b).

CONCLUSION

In view of the remarks set forth above, the applicants hereby elect the subject matter of Group II for examination, with traverse.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **322732000401**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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